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09/732,047	12/07/2000	Edwin F. Ullman	BEH-7385	9672

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EXAMINER

VENCI, DAVID J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/732,047

Applicant(s)

ULLMAN ET AL.

Examiner

David J Venci

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 7, 8 and 10-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Invention I (A1)(B1) in the reply filed on September 13, 2004 is acknowledged.

With respect to Groups II and III, Applicants discuss the possibility that prior art that might anticipate claim 26 would also anticipate or render obvious the invention of claim 25. Applicants' arguments with respect to Groups II and III are persuasive. Accordingly, claims 25 and 26 are regrouped together into Group II.

With respect to Groups II (i.e. claims 25 and 26) and Group IV (i.e. claim 27), Applicants arguments have been carefully considered but are not persuasive for the reasons set forth the prior Office Action. Accordingly, the requirement is still deemed proper and is therefore made FINAL.

Currently, claims 1-6 and 9 are before the Examiner.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title is not descriptive because the concept of luminescence is not recited in claim 1. Also, the claimed assay does not appear to be homogeneous.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the recitation of the term "substrate" is indefinite because Applicants' specification appears to use the term "substrate" interchangeably with "product" and "surface." For example, Applicants describe a "substrate" that is associated with, and releasable from, a "support" (see p. 4, lines 20-21, "oxidant cleavable linker may be used to attach substrate molecules... to a surface") (see p. 5, lines 11, "release of the substrate"). However, Applicants also describe a "product" that is associated with, and releasable from, a "support" and a "substrate" (see p. 4, lines 24-26, "The resulting detectable product is released from the surface or support and is physically separated from the substrate by centrifugation, decantation...") (see p. 5, lines 13-14, "the invention does not require separation of the product from the substrate").

In claim 1, the recitation of the term "ligand" is indefinite because Applicants' specification appear to use the term "ligand" interchangeable with "analyte." For example, Applicants describe a protein "ligand" that is coupled to a support (see p. 6, lines 9-11, "the reversible coupling of a ligand... to a molecule, support, or surface") (see p. 10, lines 26-27, "ligand analytes will normally be... polypeptides and proteins, polysaccharides, nucleic acids"). However, Applicants also describe a "ligand" as an analyte (see p. 10, lines 19-20, "The

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analyte... may be a ligand") and a "ligand" as being any organic compound (see p. 14, line 18, "Ligand' refers to any organic compound"). Therefore, the identity of a "ligand associated with the support" is not clear. In addition, the function of said "ligand" in the method is not clear. It is not clear whether either the first specific binding pair member or the second specific binding pair member binds to said "ligand" or whether said "ligand" serves a function in the step of detecting the released detectable substrate.

In claim 1, the recitation of "associated" and "association" is indefinite because it is not clear what type of spatial relationship is created by an "association" or which entities comprise or consist of an "association." Furthermore, a person of ordinary skill in the art cannot ascertain the standard or degree of association required by "associated" and "association."

In claim 1, the recitation of "cleavable linker" is indefinite because it is not clear whether the method requires an actual cleaving step.

Claim 1 is further rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. In the step of exciting the sensitizer, it is not clear how, or by what mechanism, excitation of sensitizer causes release of detectable substrate from the support. There appears to be no causal relationship between sensitizer excitation and release of substrate.

In claim 2, the recitation of "association" is indefinite for the reasons set forth supra. In addition, the recitation of "specifies" appears to be a grammatical error.

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In claim 3, the recitations of "LOCI, FOCl, ELISA, RIA" and "FETI" lack antecedent basis. It is also unclear how Luminescence Oxygen Channeling Immunoassay (LOCI) or Fluorescence Oxygen Channeling Immunoassay (FOCI) or Fluorescence Energy Transfer Immunoassay (FETI) can be incorporated into Applicants' invention when Applicants have not recited a species capable of luminescence or fluorescence. Also, it is not clear whether and/or how the recited sensitizer is used in LOCI, FOCl, or FETI. Also, the recitation of "selected from the group comprising" is indefinite because it is not clear whether Applicants intend to recite a Markush group. Also, the recitation of "avidin and anti-digoxigenin antibodies" is indefinite because it is not clear whether Applicants are claiming antibodies to avidin, digoxigenin, or both.

In claim 5, the recitation of "dioxenes, thioxenes, oxazines" is indefinite because it is not clear how cleavage of said linkers results in release of detectable substrate. It is not clear how reactive oxygen excitation, alone, would result in release of detectable substrate because it appears that cleavage of a single bond within each of said linkers would not result in complete breakage of said linkers. Also, it is not clear how "oxazines" can function as a reactive oxygen linker when Applicants have defined it as a photosensitizer in the specification (see p. 20, line 29).

In claim 6, it is not clear how cleavage of the recited linkers results in release of detectable substrate. It is not clear how reactive oxygen excitation, alone, would result in release of detectable substrate because it appears that cleavage of a single bond within each of said linkers would not result in complete breakage of said linkers.

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In claim 9, the recitation of "or indirectly" is indefinite because it is not clear what type of spatial relationship is created by "indirectly" binding or which entities are included in the binding interaction. Furthermore, a person of ordinary skill in the art cannot ascertain the standard or degree of indirectness required by "indirectly."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Singh et al. (US 6,770,439).

Singh et al. teaches a method for amplifying a signal from a binding assay comprising the steps of providing a reaction mixture comprising: a medium suspected of containing an analyte (see col. 9, lines 16-19, "a large number of proteins in a single sample"), a first specific binding pair member associated with a support (see col. 9, lines 21-22, "One group of binding proteins is bound to a support"), a second specific binding pair member associated with a sensitizer (see col. 10, lines 22-28, "Two entities are employed... that bind to the same target moiety. One of the entities generates an active species") capable in its excited state of generating a reactive oxygen species (see col. 11, line 17, "Singlet oxygen"), wherein the association of the two

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specific binding pair members is modulated by the presence of analyte (see col. 39, lines 39-41, "The resulting complex has three components, where the target serves to link the labeled binding members to the support"), and a detectable substrate associated with the support through a reactive oxygen cleavable linker (see col. 10, lines 24-27, "a susceptible functionality that interacts with the active species resulting in release of the eTag reporter") (see col. 36, lines 32-35, "The solid support may have... e-tag probe covalently or non-covalently bound to the support"), incubating the reaction mixture to allow association of the first and second specific binding pair members (see col. 39, lines 39-41, "The resulting complex has three components, where the target serves to link the labeled binding member to the support"), exciting the sensitizer causing the release of detectable substrate from the support (see col. 10, lines 24-27, "One of the entities generates an active species. The other entity has a susceptible functionality that interacts with the active species resulting in release of the eTag reporter"), and detecting the released detectable substrate (see Abstract, "Detection involves the release of identifying tags as a consequence of target recognition").

With respect to claim 2, Singh et al. teaches a method for amplifying a signal from a binding assay wherein the association of the first and second specific binding pair members results from the binding of the first and second specific binding pair members to the analyte (see col. 39, lines 35-41, "sandwich mode", "The resulting complex has three components, where the target serves to link the labeled binding members to the support"), the sensitizer is a photosensitizer (see col. 11, lines 6-7, "squarate derivatives"), the reactive oxygen is singlet oxygen (see col. 11, lines 6-7, "singlet oxygen"), and the excitation step comprises irradiation with light (see col. 10, lines 18-19, "photoactivated excited species").

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With respect to claim 3, Singh et al. teaches a method for amplifying a signal from a binding assay wherein the analyte, first specific binding pair member, and second specific binding pair member are polynucleotides (see Figs. 3A, 3B), the substrate comprises digoxigenin-linked biotin (see col. 29, lines 6-8, "biotin and strept/avidin... digoxin or derivative thereof and antidigoxin), and detection comprises avidin and anti-digoxigenin antibodies (see col. 29, lines 6-8, "biotin and strept/avidin... digoxin or derivative thereof and antidigoxin), wherein the detection method utilizes LOCI, FOCl, and FETI (see col. 10, lines 4-7, "one can use determinations involving 'channeling' or energy transfer).

With respect to claims 4-6, Singh et al. teaches a method for amplifying a signal from a binding assay wherein the reactive oxygen cleavable linker comprises enamines (see col. 11, line 20), imidazole, oxazole, and thiazole (see col. 12, lines 29-30).

With respect to claim 9, Singh et al. teaches a method for amplifying a signal from a binding assay wherein the step of detecting the released detectable substrate comprises the steps of: separating the released detectable substrate from the detectable substrate associated with the support (see col. 36, lines 19-21, "the subject heterogeneous assays require that the unbound labeled reagent be separable from the bound labeled reagent"), adding to the separated released detectable substrate, a third specific binding pair member capable of binding directly to the released detectable substrate, allowing the third specific binding pair member to bind, and detecting the bound third specific binding pair member (see col. 29, lines 6-8, "biotin and strept/avidin... digoxin or derivative thereof and antidigoxin) (see Fig. 3B).

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Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci
Examiner
Art Unit 1641

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09/30/04